

## REMARKS

The claims in the application are 17-21, 24-36 and Claims 37-39 added by the present amendment.

Favorable reconsideration of the application as amended is respectfully requested.

Claims 20 and 34 have been allowed while Claims 21-23 have been indicated allowable on page 4 of the Final Office Action. Accordingly, Claim 21 has been amended into independent form while Claims 22 and 23 have been replaced with Claims 37 and 38 respectively. Accordingly, the only outstanding issue is the art rejection of the claims.

More particularly, Claims 17-19, 24-33, 35 and 36 have again been rejected under 35 U.S.C. §103 as obvious over JP 10-30986 or JP 5-320616 in view of JP 11-178904. On page 4 of the final Office Action, the Examiner asserts nonobviousness cannot be shown by attacking these three references individually. However, it is respectfully submitted even if these three teachings are combined, then such a combined teaching still fails to suggest the claimed invention to one skilled in the art, for the following reasons.

Firstly, the arguments made in the previously-filed amendment on September 1, 2004 are respectfully reiterated and incorporated herein, especially regarding the comparative testing presented in the present application. As documented in the

present application, only samples utilizing colorless fluoran pigment in combination with an assistant having a dithiocarbamyl (or alternatively mercapto) group, were clearly colored by hydrogen peroxide low temperature plasma sterilization.

JP'986 relates to a detection material for certain gases as described below, where an electron-donating coloring organic compound (a kind of colorless type pigment) such as triphenylmethane phthalides and fluorans, along with an electron withdrawing material such as compounds having a phenolic hydroxy group, and solid acids of weak acidity, is supported on a porous matrix such as paper and cloth, or a polymeric material such as polyethylene, to thereby provide a colored detection material which is discolored and becomes colorless in contact with vapor of material having a so-called desensitizing property such as alcohols, ketones, aldehydes, ethers, esters and amines.

In this case, although the coloring fades away in the presence of the material having the so-called desensitizing property such as alcohols and esters, the original coloring state will be recovered when the desensitizing material goes away due to vaporization and the like, which is a reversible change based on ring opening of a lactone ring and ring closure to a lactone ring in the pigment molecule.

JP'616 relates to a resin composition for detecting an electron-withdrawing material, where an electron-donating coloring organic compound (a kind of colorless pigment) such as triphenylmethane phthalides and fluorans, is included in olefin thermoplastic resin such as polyethylene, to thereby provide a colorless detection material which becomes colored due to ring opening of a lactone ring in the colorless

type pigment when applied to detect the present of its electron-withdrawing material, such as phenols and carboxylic acids.

Such a composition is used for detecting electron-withdrawing material by the colorless type pigment, which is maintained in colorless state in contrast to the detection agent of JP'986 described above, being allowed to become colored by the electron-withdrawing material when in contact with the electron-withdrawing material. This also utilizes a reaction in which a lactone ring in a dye such as triphenylmethane phthalides having a lactone ring, undergoes ring opening to have a colored type structure.

JP'904 relates to an indicator for plasma sterilization where an ink which comprises a pigment, a compound having a mercapto group (-SH) (a coloring assistant) or a dithiocarbamyl group ( $>N-C(=S)-S-$ ), and a binder as essential ingredients, is printed or painted on a substrate to thereby provide an indicator for plasma sterilization which is discolored by a low temperature plasma sterilization treatment using an oxidizing gas such as hydrogen peroxide. A preferred pigment uses triphenylmethane basic pigment or a cyanine choline pigment (because of good stability in storage).

Although the indicator for plasma sterilization in JP '904 uses as pigment a triphenylmethane basic dye such as fuchsine and crista violet, the discoloration of the indicator by a low temperature plasma sterilization treatment using a hydrogen peroxide gas and the like, results from oxidative decomposition and disappearance of the dye, which is an irreversable discoloration where the originally colored state cannot be recovered with any treatment once the indicator is discolored. As a result, the

discoloration of the indicator is different from the color disappearance which occurs by ring closure to a lactone ring and recovery to a colorless type dye when the dye, with a lactone ring opened, is in contact with an electron-donating, so-called desensitizing material, as in JP '986 described above.

An indicator for plasma sterilization according to the present invention of uses, as a dye, a fluoran which is a kind of electron donating colorless type coloring dye and which is used in JP '986 and JP '616 described above. The indicator of the present invention also uses, as a coloring assistant, a compound similar to that used in JP '904, namely a compound having a dithiocarbamyl group. Thus, the present invention uses (1) a pigment common to JP '986 and JP '616, and (2) a coloring assistant common to JP '904. However, even if the content of these references is combined, the present invention is not obvious, as will be discussed below.

It is generally known a colorless type dye having a lactone ring in a molecule, such as triphenylmethanes and fluorans, tends to be colored by an oxidizing action and the like. The colorless type dye having a lactone ring as described above (which is an electron-donating material) is colored when the dye is brought into contact with a compound having a phenolic hydroxy group (which has an electron-withdrawing property) and the like, so that the lactone ring undergoes ring opening to change the dye into a colored molecular structure, as described in JP '986 and JP '616. This reaction is a kind of oxidation reaction wherein the colorless type dye which is an electron-donating material donates electrons to the compound having a phenolic hydroxy group which is an electron-withdrawing material, and the colorless type dye

itself is oxidized to be colored (consequently, a hydrogen ion  $H^+$  is donated to the colorless type dye).

However, even if an ink which is prepared by dissolving such a colorless dye and a binding agent (binder) in a solvent is painted on a substrate such as polyethylene unwoven cloth and subjected to plasma sterilization treatment using a hydrogen peroxide gas which has an oxidizing property, little coloring occurs.

After various studies, it has been found for the first time that, when the compound having a dithiocarbamyl group or a mercapto group (used in JP '904) is combined in addition to the colorless type dye, the indicator which is colorless before sterilization treatment, becomes colored by plasma sterilization treatment using a hydrogen peroxide gas.

The compound having a dithiocarbamyl group and the compound having a mercapto group used herein is the same as the compound used in JP '904. However, the indicator described in JP '904 comprises a colored triphenylmethane basic dye which is oxidatively decomposed by a plasma sterilization treatment to thereby become discolored. On the other hand, in the indicator of the present invention, a colorless type dye having a lactone ring becomes colored due to ring opening of the lactone ring by plasma sterilization treatment. Accordingly, the pigment used and coloring reaction mechanism in the present invention are different from those in JP '904.

In addition, a compound having a dithiocarbamyl group used as a coloring assistant, for example tetraethylthiram disulfide and the like, is not an electron-withdrawing material. Thus, the compound itself does not serve to allow a colorless dye

to be colored. (If the coloring assistant used is an electron-withdrawing material, then the prepared indicator is colored before the plasma sterilization treatment.)

From the forgoing, the present invention has first established an indicator using a colorless type pigment such as triphenylmethane phthalides or fluorans in combination with a compound having a dithiocarbamyl or mercapto group (a coloring assistant) can be colored due to ring opening of a lactone ring in the colorless pigment by a plasma sterilization treatment. Next, when the indicator using various kinds of colorless dyes having a lactone ring and the above-stated coloring assistants is subjected to a plasma sterilization treatment, the indicator using a colorless dye other than fluorans (such as triphenylmethane phthalides and n-dolylphthalides) becomes colored. However, the color density is not clearly improved and the coloring is unstable. It has been ascertained this is because the colored dye which was produced by ring opening of a lactone ring in the molecule is oxidatively decomposed by plasma sterilization treatment to thereby disappear. (This disappearance by oxidative decomposition of the colored dye is considered to be caused by the same principle as the color disappearance of the indicator in JP '904).

To the contrary, it has now been found that any indicator using only fluorans as a colorless pigment can be practically used as an indicator for plasma sterilization because that type of indicator is definitely improved in color density along with the treatment duration of the plasma sterilization treatment without exception. These findings have been explicitly documented by the comparative testing in the present application. In addition, a colored dye having a structure in which a lactone ring in a

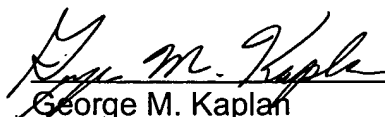
molecule of fluoran is opened is called a rhodamine dye. It has already been confirmed that the rhodamine dye has the property of being difficult to oxidatively decompose by plasma sterilization treatment even in the presence of a coloring assistant used in the present invention. Accordingly, the present invention has also found fluorans are required to be used as a colorless type dye (Therefore, colorless type dyes other than fluorans have been excluded in Claim 39.).

Therefore, the present invention is not rendered obvious even if the contents of the three cited references are combined.

Accordingly, in view of the forgoing amendment and accompanying remarks, it is respectfully submitted all claims pending herein are in condition for allowance. Please contact the undersigned attorney should there be any questions. A Petition under 37 C.F.R. § 1.136(a) for a one month extension of time to respond is enclosed, together with the requisite petition fee and fee for the additional claims introduced herein.

Early favorable action is earnestly solicited.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "George M. Kaplan", is written over a horizontal line.

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